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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,498	09/13/2004	Jean-Yves Reginster	P70086US0	8559

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EXAMINER	
FOSTER, CHRISTINE E	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,498	REGINSTER ET AL.	
	Examiner	Art Unit	
	Christine Foster	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Specifically, the oath does not provide the residence address for Inventor Stephan Christgau.

Sequence Compliance

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1 .821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1 .821 through 1 .825 for the reason(s) set forth below.

It appears that while Applicant has successfully submitted sequences in a computer readable form, the specification is not compliant with sequence rules. **For example, page 9, line 15 of the disclosure; the abstract; and claims 1, 10, and 13 refer to amino acid sequences that are not accompanied by SEQ ID number.**

If the noted sequence(s) is in the sequence listing filed, Applicants must amend the specification to identify the sequence appropriately by SEQ ID NO. If the noted sequence(s) is

not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Applicant is required to review the instant application for compliance with the requirements of applications which contain sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g).

Applicant's time to comply with the sequence rules is set forth on the attached Office Action Summary (Form PTOL-326). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to methods of assay of collagen type II or fragments thereof.

Group II, claim(s) 10-16, drawn to an immunological binding partner and kit comprising same.

4. The inventions listed as Groups I-II above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-II do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking the inventions is that of an immunological binding partner that recognizes an epitope comprised in the amino acid sequence HRGYPGLDG (SEQ ID NO:1).

Holmdahl et al. (US 7,148,020 B2) teaches the peptide GHRGYPGL (SEQ ID NO:22), which consists of amino acids 1-7 of the 9-amino acid HRGYPGLDG peptide (SEQ ID NO:1) as disclosed in the instant specification, plus an additional N-terminal Gly residue. See column 11, line 66 to column 12, line 25, and especially at column 12, lines 15-17; and column 59, entry for SEQ ID NO:22).

In particular, the Holmdahl et al. peptide is highly related to the SEQ ID NO:1 peptide as seen in the alignment below (boldfaced residues indicate identical residues in common):

Holmdahl et al. SEQ ID NO:22 peptide: G**HRGYPG**L

Instant specification SEQ ID NO:1 peptide: **HRGYPGL**DG

The peptide of Holmdahl et al. therefore shares 7 contiguous amino acids in common with the SEQ ID NO:1 peptide.

Holmdahl et al. further teach an immunological binding partner (antibody in human serum samples) that is capable of specifically binding to the SEQ ID NO:22 peptide. See column 3, lines 37-64; column 17, line 47 to column 18, line 4; and especially at column 20, lines 23-62).

Harlow et al. (Antibodies: A Laboratory Manual (1988) Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY, pages 72-76), Janeway et al. (Immunobiology: the Immune System in Health and Disease (1999), Elsevier Science Ltd/Garland Publishing, New York, NY, Fourth Edition, pages 34-35), and Kuby (Immunology, W.H. Freeman and Company (1992), page 125) are relied upon as background evidentiary references in the field of immunology in order to establish that the teachings of Holmdahl et al. discussed above read on the instantly claimed feature of an immunological binding partner that recognizes an epitope comprised in the amino acid sequence HRGYPGLDG (SEQ ID NO:1).

It is well known in the art that antibodies do not contact the entire surface of their target antigen but rather bind small epitopes within said antigen. Indeed, Harlow et al. teach that peptide epitopes recognized by antibodies are generally only six amino acids in length, with some researchers reporting even smaller epitopes that can be bound by an antibody (see particularly the first sentence of the section titled "Size of the Peptide").

Comparison of the peptide of Holmdahl et al. with that of the instant application reveals that the peptides share 100% amino acid identity over a span of seven contiguous amino acids.

As such, the peptides are identical over a length that is even longer that the length that typically defines an antibody epitope.

Janeway et al. teaches that antibodies in serum (antisera) are polyclonal in nature, containing many different antibody molecules that bind to an antigen in many different ways (see p. 34-35, especially at p. 35, the second full paragraph, and Figure 2.1). As such, the antibodies in human serum taught by Holmdahl et al. would necessarily constitute a homogeneous population of antibodies that bind to the peptide in different ways, i.e. to different epitopes of the peptide.

Further, the art also recognizes the well-known immunological phenomenon of cross-reactivity. As taught by Kuby:

"Although the antigen-antibody reaction is highly specific, in some cases antibody elicited by one antigen can cross-react with an unrelated antigen. Such cross-reactions occur if two different antigens share an identical epitope or if antibodies specific for one epitope also bind to an unrelated epitope possessing similar chemical properties." (see the left column of page 125).

In the instant case, the peptide of Holmdahl et al. is highly related to that of the instant application, sharing in common a contiguous stretch of seven amino acids, which is longer than the length that typically defines an antibody epitope.

As such, and especially in the absence of evidence to the contrary, it appears that the serum antibodies disclosed by Holmdahl et al. as binding to SEQ ID NO:22 would also bind to SEQ ID NO:1. This is due to the high degree of sequence identity amongst the two polypeptide sequences, the fact that antibodies only bind a small epitope within a larger polypeptide antigen,

and the fact that cross reactivity is routinely seen in the art wherein an antibody for a given antigen binds an identical or nearly identical epitope present in a different antigen. Although it is possible that certain individual antibodies would bind an epitope that included the N-terminal glycine residue of the Holmdahl et al. peptide (which is not present in the instant SEQ ID NO:1 peptide), because antibodies in serum are a polyclonal, heterogeneous population, some of the antibodies in this population would necessarily that bind the SEQ ID NO:22 peptide would bind to an epitope that does not include the N-terminal glycine, and would therefore cross-react with the SEQ ID NO:1 peptide.

Thus, in light of the evidence of Harlow et al., Janeway et al. and Kuby, the antibodies in human serum that bind to SEQ ID NO:22 as taught by Holmdahl et al. can be seen to constitute "immunological binding partners" that recognize an epitope within SEQ ID NO:1.

Therefore, the technical feature linking the inventions of Groups I-II does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, Groups I-II are not linked by the same or a corresponding special technical feature so as to form a single general inventive concept.

5. A telephone call was made to Mr. Jiwen Chen on 2/22/07 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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